

REMARKS

Favorable reconsideration is respectfully requested.

The claims are 11 to 21 with claim 19 being withdrawn from consideration.

Claim 11 has been rejected for failure to comply with the written description requirement for all antineoplastic agents, solvents and solvent systems.

In reply, a sufficiently wide range of antineoplastic agents and solvents are disclosed so there is no reason to doubt that applicants are in possession of the invention comprising generically, antineoplastic agents and solvents.

The nature of the antineoplastic agents and solvents is not even the essence of the invention which is the treatment of the entire formulation, including the active ingredient, with a cationic exchange resin, thereby achieving better storage properties.

Accordingly, the rejection under 35 U.S.C. 112 - written description - is untenable and should be withdrawn.

Claims 11 to 18, 20 and 21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nikolayev et al. (U.S. 5,925,776).

This rejection is also respectfully traversed.

Nikolayev et al. disclose that only polyethoxylated castor oil is subjected to a treatment with a strong cationic exchange resin. Nothing is disclosed concerning the treatment of Paclitaxel with such resin.

According to the present invention, the whole formulation (including the active ingredient - Paclitaxel) is treated with a cationic exchange resin, thereby achieving better storage properties.

It could not be foreseen that treatment not only of the solubilizing agent, but of the whole formulation, results in better storage (i.e. less decomposition of Paclitaxel in the solution).

Enclosed is a Comparative Example comprising the formulation of the present application and the formulation treated according to Nikolayev et al. See attached Table.

Thus, it is clear that the treatment of the entire composition in accordance with the present invention produces dramatically and unexpectedly improved storage properties.


For the foregoing reasons, the rejection on Nikolayev et al. is untenable and should be withdrawn.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

Respectfully submitted,

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Comparative Example

Example	1		2	
	Poly(oxyethylene)-castor oil: Ethanol = 10:90 according to the invention		Poly(oxyethylene)-castor oil: Ethanol = 10:90 according to WO 99/033780 (Nikolayev et al., U.S. 5,925,776)	
Storage condition	Start	60°C/ 2 weeks	Start	60°C/ 2 weeks
HPLC-content [%]	108.8	107.93	106.48	105.49
contamination [%]				
10-deacetyl-baccatin III	<0.1	<0.1	<0.1	<0.1
Baccatin III	<0.1	<0.1	<0.1	<0.1
(2R,3S)-N-benzoylphenyl isoserine ethyl ester	<0.1	<0.1	<0.1	<0.1
10-deacetyl-paclitaxel	<0.1	<0.1	<0.1	0.1
Cephalomannine	<0.1	<0.1	<0.1	0.3
10-deacetyl-7-epipaclitaxel	<0.1	<0.1	<0.1	<0.1
7-epipaclitaxel	<0.1	<0.1	<0.1	0.2
contamination, overall	0.6	0.5	0.8	1.2

